UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

RICHARD EIDSON,

Plaintiff,

v.

MEDTRONIC, INC.; MEDTRONIC SOFAMOR DANEK USA,INC.,

Defendants.

SCOTT BELL AND APRIL BELL,

Plaintiffs,

v.

MEDTRONIC, INC.; MEDTRONIC SOFAMOR DANEK USA,INC.,

Defendants.

Case Nos.: 13-CV-02049
13-CV-01502

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO DISMISS RICHARD EIDSON'S COMPLAINT AND SCOTT AND APRIL BELL'S COMPLAINT

Plaintiffs Scott and April Bell ("the Bells") commenced this action on April 3, 2013, alleging that Scott Bell suffered harmful side effects following a spinal fusion operation in which his surgeon used a spinal fusion device produced by Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Defendants"). ECF Bell No. 37, 13-CV-01502, Bell First

Amended Complaint (hereinafter "Bell complaint").[1] Plaintiff Richard Eidson ("Eidson") brought this action on May 6, 2013, also based on harmful effects he suffered after undergoing spinal surgery in which his surgeon used the same medical device produced by Defendants. ECF Eidson No. 38, 13-CV-02049, Eidson First Amended Complaint (hereinafter "Eidson complaint"). The two cases have been related because they involve the same product and similar questions of law. ECF Bell No. 23. On October 3, 2013, the Court granted Defendants' motion to dismiss the Bells' complaint and granted in part and denied in part Defendants' motion to dismiss Eidson's complaint. *Eidson v. Medtronic, Inc.*, 2013 WL 5533081 (N.D. Cal. Oct. 3, 2013) ("October 3, 2013 Order"). The Court held that all of the Bells' claims were barred by the statute of limitations, and that all of Eidson's non-fraud claims were either preempted or failed to show a causal nexus between Eidson's injuries and Defendants' conduct. *Id.* at *14, *16-18. The Court also held that Eidson's fraud-based claims were not preempted and were pled with sufficient particularity under Federal Rule of Civil Procedure 9(b). *Id.* at *11. Both the Bells and Eidson were granted leave to amend.

Defendants now move to dismiss both amended complaints pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted. ECF Bell No. 42; ECF Eidson No. 39. This Order addresses both motions to dismiss.

The Court vacated the hearing on Defendants' motion to dismiss the Eidson complaint. ECF No. 57. The Court held a hearing on Defendants' motion to dismiss the Bell complaint on May 8, 2014 concerning only the statute of limitations issue. Having considered the submissions and oral arguments of the parties, the relevant law, and the record in this case, the Court GRANTS IN PART with prejudice and DENIES IN PART Defendants' motion to dismiss the Eidson complaint, and GRANTS IN PART with prejudice and DENIES IN PART Defendants' motion to dismiss the Bell complaint.

[1] As this Order addresses two related cases brought by different plaintiffs, this Order will continue to follow the convention established by this Court's October 3, 2013 Order by using the following nomenclature for docket numbers in the Bell case: "ECF Bell No. X," and the following nomenclature for docket numbers in the Eidson case: "ECF Eidson No. X."

I. BACKGROUND

A. Factual Allegations

1. Infuse Device and Premarket Approval

The Court reviewed the factual background of these cases in its October 3, 2013 Order. *See Eidson*, 2013 WL 5533081, at *1-3. Here, the Court briefly notes the relevant facts.

Medtronic Sofamor Danek, USA, Inc. manufactures a medical device known as the Infuse Device ("Infuse") which stimulates bone growth in spinal fusion surgeries. Bell Complaint ¶ 2; Eidson Complaint ¶ 2. Infuse consists of three components: (1) the active ingredient, a liquid form of the protein rhBMP–2 which stimulates bone growth, (2) a metallic spinal fusion cage (the "LT Cage") to stabilize and hold in place the liquid protein, and (3) a spongy carrier for the protein. *Id.* ¶ 34; *Id.*¶ 33. The FDA in July 2002 granted Infuse premarket approval ("PMA") as a medical device under the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"). *Id.* ¶¶ 58, 63; *Id.* ¶¶ 45, 60. Following this approval, Defendants were permitted to sell the Infuse Device. *Id.* ¶ 44; *Id.* ¶ 43.

The FDA's approval letter stated that the Device may be implanted (1) from the anterior (front) abdomen, (2) for purposes of a single-level fusion, (3) within lumbar spine levels L4 through S1, and that Infuse must not be used without the LT Cage. *Id.* ¶¶ 65, 66; *Id.* ¶ 64. Any operation that uses the Device in a manner other than that approved by the FDA is called an "off-label" use. *Id.* ¶ 67; *Id.* ¶ 66. This includes operations in which the spine is approached from the back and operations without the LT Cage. *Id.* ¶¶ 4, 69; *Id.* ¶¶ 4, 68. During approval hearings, FDA officials expressed concern about potential side effects stemming from off-label use and advised Defendants to take steps to prevent such use. *Id.* ¶¶ 70, 73, 75-77; *Id.* ¶¶ 72-76.

Plaintiffs allege that beginning in 1999, Defendants were aware that medical studies had found evidence of severe side effects associated with the off-label use of Infuse, particularly excessive bone growth. *Id.* ¶¶ 103-105; *Id.* ¶¶ 104-105, 123. Despite this knowledge, Defendants embarked on a vigorous campaign to promote off-label uses of Infuse by establishing consulting/royalty agreements with physicians who advocated off-label uses. *Id.* ¶¶ 120-121, 179-

184; *Id.* ¶¶ 119-120, 178-183. Defendants also funded studies and articles by opinion leaders that omitted mentions of the risks of off-label use or understated the incidence of adverse effects. *Id.* ¶¶ 105, 127; *Id.* ¶¶ 71, 104, 126. In addition, Defendants failed to report adverse events suffered by patients who used Infuse off-label to the FDA, and by April 2008 Defendants had reported only 262 of an estimated 50,000-250,000 adverse events. *Id.* ¶ 319; *Id.* ¶ 309. This failure to report led to the omission of these events from the FDA's publicly accessible MAUDE database. *Id.* ¶¶ 113, 280; *Id.* ¶¶ 111-112, 279. These activities led to investigations by the Department of Justice resulting in a $40 million settlement and Corporate Integrity Agreement on July 18, 2006. *Id.* ¶¶ 146-150; *Id.* ¶¶ 145-149. Defendant's promotion of off-label use also led to significant controversial media coverage in the *Wall Street Journal* and the *New York Times. Id.* ¶¶ 96, 185, 191; *Id.* ¶¶ 95, 184, 190-191.

2. Scott Bell's surgery

In February 2005, Scott Bell underwent a spinal fusion operation in which his surgeon, Dr. Seago, used Infuse in an off-label manner by implanting it by posterior approach and by failing to use an LT Cage. Bell Complaint ¶ 286. The Bells allege that Defendants directly and indirectly encouraged his surgeon to use an off-label procedure. *Id.* ¶ 287. Dr. Seago did not inform the Bells that the operation would involve rhBMP-2, and the surgical consent form Mr. Bell signed inaccurately implied that the surgery would instead involve a natural iliac crest bone graft. *Id.* ¶ 290, 292. Only the hospital's "sticker page" of equipment used in the procedure notes the use of an artificial protein graft. *Id.* ¶ 293. After his surgery, Scott Bell experienced increased pain and was told by Dr. Seago that this was due to a "biological phenomenon." *Id.* ¶ 291. On March 2, 2007, Scott Bell was diagnosed with advanced bony overgrowth in the area of his spine targeted by the surgery. *Id.* ¶ 288. Scott Bell underwent corrective surgery for this overgrowth on May 3, 2007. *Id.* Neither Dr. Seago nor any of Scott Bell's other physicians ever informed him that Infuse was used in his surgery and may have contributed to his side effects. *Id.* ¶¶ 294-296.

As a result, Plaintiffs Scott and April Bell bring five causes of action against Defendants in connection with Infuse: (1) fraudulent misrepresentation/fraud in the inducement (*id.* ¶¶ 299–311);

(2) strict products liability—failure to warn (*id.* ¶¶ 312–327); (3) negligent misrepresentation (*id.* ¶¶ 328–338); (4) negligent failure to warn (*id.* ¶¶ 329–353); and (5) loss of consortium on behalf of April Bell (*id.* ¶¶ 354–356).

3. Richard Eidson's surgery

On November 11, 2008, Plaintiff Richard Eidson underwent a spinal fusion operation that utilized Infuse in an off-label manner by implanting the device from the back, by using a multi-level fusion, and by failing to use an LT Cage. Eidson Complaint ¶ 285. Eidson alleges Defendants directly and indirectly encouraged his surgeon, Dr. Smith, to use an off-label procedure. *Id.* ¶ 285-286. After the surgery, Eidson began experiencing pain, weakness, decreased sensation, and decreased reflexes in his legs and back pain. *Id.* ¶ 287. On May 14, 2012, he was diagnosed with fluid-filled cysts within the vertebral bodies where the surgery had taken place, and now has severe pain, reduced sensation, strength, and reflexes in his lower extremities. *Id.* ¶ 288. He has also suffered bone resorption and bone overgrowth. *Id.* ¶ 12.

As a result, Eidson brings four causes of action against Defendants in connection with Infuse: (1) fraudulent misrepresentation/fraud in the inducement (*id.* ¶¶ 290–302); (2) strict products liability—failure to warn (*id.* ¶¶ 303–317); (3) negligent misrepresentation (*id.* ¶¶ 318–328); and (4) negligent failure to warn (*id.* ¶¶ 329–342).[2]

[2] Both Plaintiffs' First Amended Complaints include two causes of action (negligent misrepresentation and negligent failure to warn) not included in their original complaints. Plaintiffs justify the inclusion of these new causes of action by insisting that they allege the same misconduct set forth in the "Strict Liability – Misrepresentation" claims in their original complaints and that Plaintiffs have merely "relabeled" that claim. Bell MTD Opp'n at 10-11; Eidson Opp'n at 7-8. The Court's October 3, 2013 Order advised Plaintiffs that they would not be permitted to "add new parties or causes of action without a stipulation or order of the Court." *Eidson*, 2013 WL 5533081 at *18. Although Plaintiffs have violated the Court's Order, the Court will not require Plaintiffs to formally move for leave to amend their complaints before the Court rules on Defendants' pending motions to dismiss. In order to avoid delay on Defendants' motion to dismiss, the Court simply construes the Plaintiffs' alteration of their complaints as a motion to amend under Federal Rule of Civil Procedure 15. Under Rule 15(a), leave to amend "should be freely granted when justice so requires." *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (internal quotation marks omitted). Because Defendants, in their oppositions, have not objected to the fact that Plaintiffs have included new causes of action, the Court grants Plaintiffs' motion for leave to amend. The Court warns Plaintiffs, however, that should they include new causes of action in the future without a stipulation or Court order, those causes of action will be dismissed with prejudice.

B. Procedural History

Plaintiffs Scott and April Bell filed their original complaint on April 3, 2013. ECF Bell No. 1. Defendants filed a Motion to Dismiss the Complaint on May 14, 2013. ECF Bell No. 10. Plaintiffs filed an opposition to the Motion to Dismiss on July 1, 2013. ECF Bell No. 20. Defendants filed a reply on July 22, 2013. ECF Bell No. 24.

Plaintiff Richard Eidson filed his complaint on May 6, 2013. ECF Eidson No. 1. Defendants filed a Motion to Dismiss the Complaint on May 28, 2013. ECF Eidson No. 9. Plaintiff filed an opposition to the Motion to Dismiss on July 1, 2013. ECF Edison No. 18. Defendants filed a reply on July 22, 2013. ECF Eidson No. 21.

On October 3, 2013, the Court granted Defendants' motion to dismiss as to the Bells' claims and granted in part and denied in part Defendants' motion to dismiss as to Eidson, giving both plaintiffs leave to amend.

Plaintiffs Scott and April Bell filed a First Amended Complaint on November 15, 2013. ECF Bell No. 37. Defendants filed a Motion to Dismiss the First Amended Complaint on January 8, 2014. ECF Bell No. 42 ("Bell MTD"). Plaintiffs filed an opposition on February 7, 2014. ECF Bell No. 46 ("Bell MTD Opp'n"). Defendants filed a reply on February 21, 2014. ECF Bell No. 47.

Plaintiff Richard Eidson filed a First Amended Complaint on November 15, 2013. ECF Eidson No. 38. Defendants filed a Motion to Dismiss the First Amended Complaint on January 8, 2014. ECF Eidson No. 39 ("Eidson MTD"). Plaintiff filed an opposition on February 7, 2014. ECF Edison No. 46 ("Eidson Opp'n"). Defendants filed a reply on February 21, 2014. ECF Eidson No. 47 ("Eidson Reply").[3]

II. LEGAL STANDARDS

A. Motion to Dismiss Under Rule 12(b)(6)

[3] Defendants filed notices of supplemental authorities on March 7, 2014, March 13, 2014, March 20, 2014, March 27, 2014, April 8, 2014, April 16, 2014, and April 30, 2014. ECF Bell Nos. 48, 49, 50, 51, 53, 54, 55; ECF Eidson Nos. 48, 49, 50, 51, 52, 53, 54. The Court has considered these supplemental authorities.

Federal Rule of Civil Procedure 12(b)(6) permits a party to move to dismiss a complaint for failure to state a claim upon which relief can be granted. To survive a motion to dismiss, a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). A claim is plausible when the plaintiff pleads "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). For purposes of ruling on a Rule 12(b)(6) motion, a court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir.2008). Moreover, the court "presume[s] that general allegations embrace those specific facts that are necessary to support the claim." *Nat'l Org. for Women v. Scheidler*, 510 U.S. 249, 256, 114 S.Ct. 798, 127 L.Ed.2d 99 (1994), *quoting Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). A complaint's non-conclusory factual allegations and reasonable inferences drawn from them, "must be plausibly suggestive of a claim entitling the plaintiff to relief." *Moss v. United States Secret Serv.*, 572 F.3d 962, 970 (9th Cir.2009), *citing Iqbal*, 129 S.Ct. at 1949.

A court is not required, however, to " 'assume the truth of legal conclusions merely because they are cast in the form of factual allegations.' " *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th Cir.2011) (per curiam) (quoting *W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981)). A court also need not accept as true allegations contradicted by judicially noticeable facts, *Shwarz v. United States*, 234 F.3d 428, 435 (9th Cir. 2000). Mere "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss." *Adams v. Johnson*, 355 F.3d 1179, 1183 (9th Cir. 2004); *accord Iqbal*, 556 U.S. at 678, 129 S.Ct. 1937.

B. Federal Rule of Civil Procedure 9(b)

When sitting in diversity, a court applies Federal Rule of Civil Procedure 9(b)'s heightened pleading standard to any state law causes of action sounding in fraud or deceit. *See Vess v. Ciba–Geigy Corp. USA*, 317 F.3d 1097, 1103 (9th Cir. 2003). Rule 9(b) provides that "[i]n alleging fraud

or mistake, a party must state with particularity the circumstances constituting fraud or mistake." A complaint must "be 'specific enough to give defendants notice of the particular misconduct . . . so that they can defend against the charge and not just deny that they have done anything wrong.' " *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (citation omitted). The complaint must include facts regarding the "time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *Edwards v. Marin Park, Inc.*, 356 F.3d 1058, 1066 (9th Cir. 2004) (citation omitted). In addition, "[t]he plaintiff must set forth what is false or misleading about a statement, and why it is false." *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc), *superseded by statute on other grounds.*

C. Leave to Amend

If the Court determines that the complaint should be dismissed, it must then decide whether to grant leave to amend. Under Rule 15(a) of the Federal Rules of Civil Procedure, leave to amend "should be freely granted when justice so requires," bearing in mind that "the underlying purpose of Rule 15 . . . [is] to facilitate decision on the merits, rather than on the pleadings or technicalities." *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (internal quotation marks omitted). Nonetheless, a court "may exercise its discretion to deny leave to amend due to 'undue delay, bad faith or dilatory motive on part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party. . . , [and] futility of amendment.'" *Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 892-93 (9th Cir. 2010) (alterations in original) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

D. Requests for Judicial Notice

While a court generally may not consider evidence or documents beyond the complaint in the context of a Rule 12(b)(6) motion to dismiss, Federal Rule of Evidence 201(d) provides that "[a] court shall take judicial notice [of an adjudicative fact] if requested by a party and supplied with the necessary information." A court may take judicial notice of any fact that is "not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the

trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot be reasonably questioned." *Id*.

A court may consider documents "whose contents are alleged in a complaint and whose authenticity no party questions," despite such documents not being physically attached to the pleadings. *Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005). A court may also take judicial notice of "matters of public record outside the pleadings." *Mack v. S. Bay Beer Distribs., Inc.*, 798 F.2d 1279, 1282 (9th Cir.1986), *overruled on other grounds by Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 111 S.Ct. 2166, 115 L.Ed.2d 96 (1991). While matters of public record are proper subjects of judicial notice, a court may take notice only of the authenticity and existence of the documents, not the veracity or validity of their contents. *See Lee v. City of Los Angeles*, 250 F.3d (9th Cir. 2001).

Defendants have filed Requests for Judicial Notice in support of their motions to dismiss both Plaintiffs' complaints. ECF Bell No. 44; ECF Eidson No. 41. With regard to Defendants' motion to dismiss the Bell complaint, the documents as to which Defendants request notice are precisely the same as those contained in the Request for Judicial Notice accompanying their motion to dismiss the original complaint. *See* ECF Bell No. 11; ECF Bell No. 44. Because Plaintiffs have not filed an opposition to these requests and for the reasons set forth in this Court's October 3, 2103 Order, the Court grants all of Defendants' requests.[4]

With regard to Defendant's motion to dismiss the Eidson complaint, Exhibits A-H, for which Defendants request notice, are the same as those contained in the Request for Judicial Notice accompanying Defendants' motion to dismiss the original complaint. *See* ECF Eidson No. 10; ECF Eidson No. 41. Plaintiffs have not filed an opposition to these requests, and for the reasons set forth in this Court's October 3, 2103 Order, the Court grants Defendants' request for judicial notice with regard to those exhibits.

[4] For a full discussion of the Court's reasoning in granting all these judicial notice requests, *see Eidson*, 2013 WL 5533081, at *5-6.

However, Defendants also request judicial notice of one document not contained in the Request for Judicial Notice accompanying their motion to dismiss the original complaint. The newly included document, Exhibit I, consists of a Medtronic "Important Medical Information" label regarding the use of Infuse. ECF Eidson No. 41, at 2. Defendants assert that Exhibit I is the warning label in effect at the time of Eidson's surgery. *Id.* at 3-4. The Court based its grant of all Defendants' previous requests on the fact that "all of the documents at issue appear on the FDA's public website," and were matters of the public record. *Eidson*, 2013 WL 5533081, at *5-6. With regard to Exhibit I, however, Defendants provide no citation to any FDA website or publication, and the label itself is a creation of Medtronic rather than the FDA. Exhibit I thus does not qualify as a matter of public record. Nonetheless, the Court grants the request for judicial notice. Defendants invoke the doctrine of incorporation by reference, claiming that the Eidson complaint challenges the sufficiency of the Infuse warning label and thus incorporates that label by reference. ECF Eidson No. 41, at 3-4. The Court agrees. Eidson's complaint asserts that any warnings issued by Defendants regarding the dangers of off-label use were "insufficient in light of" Defendant's promotional activities. Eidson Complaint ¶ 309(iii). Accordingly, Eidson directly challenges the sufficiency of the FDA-approved warnings and the contents of those warnings are thus incorporated in his complaint. Moreover, Eidson has not opposed Defendants' Request for Judicial Notice of Exhibit I nor questioned its authenticity. Thus, because a court may consider documents "whose contents are alleged in a complaint and whose authenticity no party questions," *Knievel*, 393 F.3d at 1076, the Court takes judicial notice of Exhibit I.

III. REGULATORY BACKGROUND AND PREEMPTION LAW

Before addressing Defendants' arguments, the Court sets forth the regulatory background and legal framework for preemption.

A. Federal Regulation of Medical Devices

In 1976, Congress enacted the MDA, which "imposed a regime of detailed federal oversight" over the entry of medical devices. *Riegel v. Medtronic*, 552 U.S. 312, 316 (2008). Notably, a process of premarket approval was established for new Class III devices. *Id.* at 316–17.

Premarket approval is a "rigorous" process in which the manufacturer submits to the FDA extensive reports, design specifications and descriptions, samples of the device, and proposed labeling, and the FDA spends an average of 1,200 hours per application reviewing and evaluating these materials. *Id.* at 317-18. The FDA then "weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," and "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* (internal quotation marks omitted).

B. Federal Preemption

1. Express Preemption

Defendants move to dismiss Eidson's complaint on the ground that all of his state law claims are expressly preempted by the MDA. The MDA contains an express preemption provision:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The Supreme Court established a two-step framework for analyzing express preemption under the MDA in *Riegel*, 552 U.S. at 322. The court must first determine whether the FDA has established requirements applicable to the device at issue. If so, the court must then determine whether the plaintiff's claims are based on state requirements regarding the device that are "different from, or in addition to" the federal requirements, and that relate to the safety or effectiveness of the device. *Id.* at 321-22. If so, the plaintiff's claims are expressly preempted by the MDA. *Id*. at 316.

State law claims can escape preemption only if they are based on state duties "parallel" to federal duties stemming from the FDA regulations. *See Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc). If state law liability could be found notwithstanding compliance with the federal requirements, those state law duties are not parallel to the federal requirements and will be preempted. *See Riegel*, 552 U.S. at 328. "To properly plead parallel claims that survive

preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation." *Erickson v. Boston Scientific Corp.*, 846 F.Supp.2d 1085, 1092 (C.D. Cal. 2011) (internal quotation marks omitted).

2. Implied Preemption

The MDA also prohibits suits by private litigants to enforce the provisions of the Act, requiring that all such actions "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court, in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), interpreted this provision as impliedly preempting claims seeking to enforce an exclusively federal requirement not grounded in traditional state tort law. *See id.* at 352-53.

The Supreme Court in *Buckman* impliedly preempted a plaintiff's claims alleging that a device manufacturer made misrepresentations to the FDA during the PMA process. *Id.* at 348 ("[T]he plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law"). However, courts have made clear that *Buckman* should not be read to foreclose claims based on any conduct that violates the FDCA. Rather, state law claims may avoid preemption if they rely on traditional state tort law duties which predate the FDCA requirements. *See, e.g.*, *Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 776–77 (D. Minn. 2009) (to escape preemption, conduct forming the basis of claims "must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted."). In sum, a claim is impliedly preempted under *Buckman* if it is cognizable only by virtue of the provisions of the FDCA itself, and would not be independently viable under state law; conversely, a state law cause of action escapes implied preemption if it would state a claim under state law even in the absence of the FDCA. *See Buckman*, 531 U.S. at 348.

Together, express preemption and implied preemption provide only a "narrow gap" through which a plaintiff's claims must fit in order to survive. *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013) ("The plaintiff must be suing for conduct that *violates* the FDCA (or else his

claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).") (emphasis in original) (citation omitted).

IV. ANALYSIS

A. Analysis of Defendant's Argument that the Bells' Claims are Time-Barred

The Court first addresses Defendants' argument that all of the Bells' claims are time-barred. Bell MTD at 4-8. In its October 3, 2013 Order, this Court dismissed the Bells' claims with leave to amend, finding that the claims were barred by the statute of limitations because the Bells' complaint did not allege sufficient facts regarding the discovery rule. *Eidson*, 2013 WL 5533081, at *16-18. The Court finds that the Bells have now alleged sufficient facts to plead the discovery rule, and thus rejects Defendants' argument that all of the Bells' claims are time-barred.

In their amended complaint, the Bells have included the following assertions regarding their delay in discovering Defendants' wrongdoing and filing their suit:

(1) "At the time of his surgery on February 24, 2005, Dr. Randall Seago did not inform plaintiff Scott Bell that he was using rhBMP-2 by any name (INFUSE®, BMP), and did not obtain his consent to use rhBMP-2." Bell Complaint ¶ 290.

(2) "Mr. Bell's consent form does not mentioned [sic] rhBMP, BMP, or INFUSE®. Instead, … the consent implies that bone was to be taken from Mr. Bell's iliac crest, not that INFUSE® would be used." *Id*. at ¶ 292.

(3) "The operative report itself does not mentioned [sic] the use of rhBMP-2. Only the separate 'sticker page,' which is the hospital's record of devices and equipment used during the procedure, mentions the use of rhBMP-2." *Id*. at ¶ 293.

(4) "When plaintiff Scott Bell experienced increased pain after his surgery, Dr. Randall Seago told him that his pain was due to a 'biological phenomenon' in terms of the way Mr. Bell's body uniquely reacted to surgery. Dr. Seago did not state, or imply in any way, that Mr. Bell's pain and other symptoms were potentially the result of any product used during the surgery." *Id*. at ¶ 291.

(5) "At no time did any of Scott Bell's treating physicians inform him that rhBMP-2 had been used in his surgery." *Id*. at ¶ 294.

(6) "At no time did any of Scott Bell's treating physicians inform him that any product defect of failure might have caused or contributed to his new symptoms." *Id.* at ¶ 295.

(7) "Until April 2012, Scott Bell had no reason to suspect, and did not suspect, that any product defect or failure might have caused his symptoms." *Id.* at ¶ 296.

(8) "In April 2012, Scott Bell's mother saw a lawyer commercial regarding lawsuits involving MEDTRONIC'S INFUSE® device. She mentioned this to Scott Bell, asking whether that device might have been used in his surgery. Within two weeks, in April 2012, Scott Bell contacted a lawyer in order to find out whether this device had been used in his surgery and might have contributed to his injuries." *Id*. at ¶ 297.

(9) "Despite diligent investigation by Plaintiff into the cause of his injuries, including numerous consultations with Mr. Bell's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to INFUSE® was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims." *Id.* at ¶ 298.

Defendants argue that the Bells have failed to plausibly allege facts regarding why their failure to file a timely claim should be excused. Bell MTD at 4-8. The Court disagrees.

A federal court sitting in diversity on a state law claim must apply the state statute of limitations. *Bancorp Leasing & Fin. Corp. v. Agusta Aviation Corp.*, 813 F.2d 272, 274 (9th Cir. 1987). Because the statute of limitations is an affirmative defense, the "defendant has the burden of proving the action is time-barred." *Grisham v. Philip Morris, Inc.*, 670 F.Supp.2d 1014, 1020 (C.D. Cal. 2009) (citation omitted). Under California Civil Procedure Code § 335.1, personal injury claims based on defective products are subject to a two-year limitations period. *Soliman v. Philip Morris Inc.*, 311 F.3d 966, 971 (9th Cir. 2002). "In ordinary ... actions, the statute of limitations ... begins to run upon the occurrence of the last element essential to the cause of action." *Gutierrez v. Mofid*, 39 Cal.3d 892, 899 (1985) (citation omitted). Therefore, for personal injury claims, the date

of accrual of the cause of action is generally the date of physical injury. *See Jolly v. Eli Lilly & Co.*, 44 Cal.3d 1103, 1109 (1988). Although the general rule provides that the statute of limitations begins to run "when the cause of action is complete with all of its elements," *Norgart v. Upjohn Co.*, 21 Cal.4th 383, 389 (1999), the discovery rule delays the commencement of the running of the statute until the plaintiff "is aware of her injury and its negligent cause." *Jolly*, 44 Cal.3d at 1109. More specifically, under the discovery rule, the statute of limitations begins to run not when the plaintiff sustains her injury, but rather "when the plaintiff suspects or should suspect that her injury was caused by wrongdoing, that someone has done something wrong to her." *Id.* at 1110. Thus, the discovery rule "delays accrual until the plaintiff has, or should have, inquiry notice of the cause of action." *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal.4th 797, 807 (2005). However, a "plaintiff whose complaint shows on its face that [her] claim would be barred without the benefit of the discovery rule must specifically plead facts to show (1) the time and manner of discovery *and* (2) the inability to have made earlier discovery despite reasonable diligence." *Id.* at 808 (citation omitted). Here, the Bells did not file their lawsuit until six years after Scott Bell sustained his injuries and underwent corrective surgery in May 2007. *Eidson*, 2013 WL 5533081, at *18. Nonetheless, the Bells argue that their claims are not barred by the statute of limitations because the discovery rule delayed the accrual of their claims. Below, the Court explains why the Bells have now pled sufficient facts to allege the delayed discovery rule. First, the Court explains why it is plausible that, as the Bells argue, the Bells were not on inquiry notice concerning the role Infuse played in causing Scott Bell's injuries until April 2012 when Scott Bell's mother saw a commercial about lawsuits concerning Infuse. Second, the Court explains why the Bells have pled sufficient facts showing (1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence.

First, the Court concludes that it is plausible that the Bells were not on inquiry notice until April 2012. The discovery rule "delays accrual until the plaintiff has, or should have, inquiry notice of the cause of action." *Fox*, 35 Cal.4th at 807. Inquiry notice occurs "when the plaintiff suspects or should suspect that her injury was caused by wrongdoing, that someone has done something

wrong to her." *Jolly*, 44 Cal.3d at 1110. "The question when a plaintiff actually discovered or reasonably should have discovered the facts for purposes of the delayed discovery rule is a question of fact unless the evidence can support only one reasonable conclusion." *Ovando v. County of Los Angeles*, 159 Cal. App. 4th 42, 61 (2008) (citing *Jolly*, 44 Cal.3d at 1112); *see also Ward v. Westinghouse Canada, Inc.*, 32 F.3d 1405, 1408 (9th Cir. 1994) ("Under California law, the question of when [the plaintiff] was on inquiry notice of potential wrongdoing is a factual question."). *See also E-Fab, Inc. v. Accountants, Inc. Services*, 64 Cal. Rptr. 3d 9, 17 (Cal. App. 6th Dist. 2007) ("Resolution of the statute of limitations issue is normally a question of fact. More specifically, as to accrual, once properly pleaded, belated discovery is a question of fact. As our state's high court has observed: 'There are no hard and fast rules for determining what facts or circumstances will compel inquiry by the injured party and render him chargeable with knowledge. It is a question for the trier of fact.' However, whenever reasonable minds can draw only one conclusion from the evidence, the question becomes one of law.") (internal citations and quotation marks omitted).

Here, in light of the Bells' allegations, the Court finds that the question of when the Bells were on inquiry notice of Defendants' alleged wrongdoing is a question of fact, and cannot be decided as a matter of law at this stage of the proceedings, because the Bells' allegations do not support only one reasonable conclusion. While Defendants argue that the only reasonable conclusion is that the Bells were on inquiry notice by May 2007 when Scott Bell underwent corrective surgery for his bony overgrowth or at the latest by 2008, Bell MTD at 8, it is plausible that the Bells were not on inquiry notice that Scott Bell's injury was caused by Infuse until April 2012. This is because the Bells allege that Scott Bell's surgeon never told him that Infuse was to be used in the 2005 surgery nor obtained Scott Bell's consent to use it. *Id.* at ¶ 290. Nor did any physician ever tell Scott Bell that Infuse had been used in his surgery. *Id.* at ¶ 294. Further, Scott Bell's surgery consent form, which did not mention Infuse, implied that the bone to be used in the surgery was to be taken from Scott Bell's iliac crest. *Id.* at ¶ 292. The Bells further allege that no physician told Scott Bell that a product defect might have contributed to his new pain or symptoms.

Id. at ¶ 295. To the contrary, when he began experiencing pain, his surgeon told him his pain was due to a " 'biological phenomenon' in terms of the way [his] body uniquely reacted to surgery." *Id.* at ¶ 291. Accepting these facts as true and construing them in Plaintiffs' favor as the Court must at this stage, the Court finds it is plausible that the Bells did not have reason to know or suspect that wrongdoing caused Scott Bell's injuries until April 2012 when Scott Bell's mother saw a commercial regarding Infuse. *Id.* at ¶ 296. This is because given Scott Bell's doctors' failure to disclose the use of Infuse in Scott Bell's surgery and representations about the cause of his pain, Scott Bell may reasonably have relied on his doctor's representations rather than trying to figure out on his own that Infuse was used during his surgery and that Infuse caused his injuries.

Defendants' arguments to the contrary are unavailing. Defendants argue that the Bells should have been on inquiry notice by May 2007 because the reasonable person would have requested his surgical records from his initial surgery after having to go through corrective surgery in May 2007. Bell MTD at 6. Defendants claim those records would have revealed the alleged wrongdoing because the Bells' own complaint concedes that the separate sticker page to the operative report, which is the hospital's "record of devices and equipment used during the procedure," mentioned the use of rhBMP-2, the protein used in Infuse. *Id.* (citing Bell Complaint at ¶ 293).[5] The Bells have also conceded that the operative report indicated the use of "Infuse," *see* ECF No. 60 (Letter from Plaintiffs' Counsel to the Court). Defendants further note how Scott Bell's pre-surgery consent form indicated that an "intervertebral fusion device" was to be used in the surgery, Bell MTD at 6 (citing Bell Complaint at ¶ 292). However, Defendants' argument is unpersuasive because it is plausible that the reasonable person would not see a need to request or inspect his surgical records if his physician failed to disclose the use of Infuse during surgery and led him to believe that a "biological phenomenon" caused his injuries. *See, e.g.*, *Unjian v. Berman*, 208 Cal. App. 3d 881, 885 (1989) (finding triable issue of fact as to delayed discovery because an

[5] In the Bells' Opposition, they also concede that the sticker page listed "the make, manufacture, model, and identifier for the devices and equipment used during [the] procedure," which means they concede that the name "Infuse" and the name of the manufacturer of Infuse, i.e., Medtronic, appeared on the sticker page. Bell Opp'n at 4.

operation's failure to produce expected result would not necessarily suggest to the ordinary person that operation had been performed negligently and a jury could reasonably conclude plaintiff was justified in accepting doctor's explanations); *Lamb v. Scripp Clinic*, 2006 WL 172070, *5 (Cal. App. 4th Dist. 2006) (reversing grant of summary judgment to defendant on statute of limitations grounds where plaintiff's doctor "responded in a manner that could lead a reasonable person to believe there was no negligence" by himself and the other doctors who participated in plaintiff's surgery); *Lucas v. Somberg*, 2006 WL 2270928, *1 (Cal. App. 2d Dist. 2006) (finding triable issue of fact as to delayed discovery, reasoning that because plaintiff "was given an explanation [by doctor] that there would be no resulting scars [from his burns], the question of his reasonable diligence in discovering his permanent scarring is one of fact"). On this point, the California court of appeal's decision in *Unjian* is illustrative. There, a plaintiff sued his plastic surgeon after unsuccessful face-lift surgery. *Id.* at 883-884. Although the plaintiff noticed shortly after the operation that his face looked " 'worse' " after the operation, he remained in the surgeon's care for ten more months and the defendant surgeon told him the problem could have been caused by a preexisting condition. *Id.* at 883. Reversing a summary judgment in favor of the plastic surgeon, the court of appeal found triable issues of fact existed as to whether California Code of Civil Procedure ¶ 340.5 was tolled by the plaintiff's delayed discovery. *Id.* at 888. The court of appeal reasoned that the fact that the operation did not produce the expected result did not necessarily connect the injury to the defendant's negligence. *Id.* at 885. The court of appeal found the plaintiff could have reasonably accepted the doctor's alternative explanation of the injury and therefore there was a triable issue as to when the plaintiff knew or should have known of the injury and its negligent cause. *Id.* at 884-888. Like in *Unjian*, it is plausible that Scott Bell reasonably accepted his doctor's explanation that a "biological phenomenon" caused his injuries and thus found no reason to inquire further.

Second, Defendants argue that even assuming the Bells were not placed on inquiry notice by May 2007, they should have been placed on notice by 2008 because their complaint alleges that the off-label use of Infuse was the subject of widespread media attention as early as July 1, 2008,

including articles that stated that off-label use could lead to bony overgrowth of the type which Scott Bell was experiencing. *See* Bell MTD at 6-7; Bell Complaint ¶ 96 (discussing September 4, 2008 Wall Street Journal article linking off-label use of Infuse to "unwanted bone growth near nerves" and stating that 75 percent of adverse events reported to the FDA involved off-label use); *id.* ¶ 201 (noting a May 19, 2009 New York Times article regarding Defendants coming under investigation by the Department of Justice for off-label promotion of Infuse); *id.* ¶ 94 (citing how FDA issued on July 1, 2008 a "Public Health Notification" warning about the "serious complications" that may arise from off-label use). Defendants' argument fails because it has been rejected by California courts. In *Unruh–Haxton v. Regents of University of California*, 162 Cal.App.4th 343, 364 (Cal. App. 4th Dist. 2008), the California court of appeal held that "public awareness of a problem through media coverage alone [cannot] create [ ] constructive suspicion for purposes of [the delayed] discovery [rule]." This is because "[t]he statute of limitations does not begin to run when some members of the public have a suspicion of wrongdoing, but only 'once the plaintiff *has* a suspicion of wrongdoing.' " *Id.* at 361 (citing *Nelson v. Indevus Pharmaceuticals, Inc.*, 142 Cal. App. 4th 1202, 1206 (Cal. App. 2d Dist. 2006) (emphasis in original)).

Similarly, in *Nelson*, the plaintiff's cause of action arose from her use of a diet drug sold as Redux. *Id.* at 1204. The defendant argued that the plaintiff's action was barred by the statute of limitations, because the limitations period began to run when the dangers of a similar drug, known as "Fen-phen," were widely publicized. *Id.* The court of appeal disagreed, finding that the plaintiff had no obligation to read newspapers and watch television news or otherwise seek out information not disclosed by her prescribing doctor. *Id.* at 1208. The court of appeal's conclusion was bolstered by Code of Civil Procedure section 340.8, the statute of limitations for claims involving toxic torts or hazardous materials, which specifically provides that "[m]edia reports regarding the hazardous material or toxic substance contamination do not, in and of themselves, constitute sufficient facts to put a reasonable person on inquiry notice that the injury or death was caused or contributed to by the wrongful act of another." *Id.* (citing Cal. Code. Civ. P. ¶ 340.8). In sum, the court of appeal

held there is no rule of "constructive suspicion" that triggers the statute of limitations simply when the dangers of a product are publicized.

Federal courts applying California law have come to similar conclusions. *See, e.g., Yumul v. Smart Balance, Inc.*, 733 F. Supp. 2d 1134, 1143 n.17 (C.D. Cal. 2010) (rejecting defendant's argument that media reports would suffice to show that plaintiff was on inquiry notice as a matter of law); *Migliori v. Boeing N. Am., Inc.*, 97 F.Supp.2d 1001, 1011 (C.D. Cal. 2000) (holding at motion to dismiss stage that "[t]he mere fact of publicity ... does not conclusively show that a plaintiff must be imputed with knowledge" and does not establish that plaintiffs' claims are time-barred as a matter of law). Here, the Bells' complaint nowhere alleges that the Bells were aware of these articles, saw them, or read them, and thus it is plausible that they were not in fact aware of such articles or information. *See Unruh-Haxton*, 162 Cal.App.4th at 363-364 (rejecting defendant's claim that publicity gave rise to plaintiffs' constructive knowledge of the media coverage); *McGill v. M.J. Brock & Sons, Inc.*, 91 Cal. Rptr. 2d 135, 142-143 (Cal. App. 4th Dist. 1999) (denying summary judgment to defendants on statute of limitations grounds and rejecting argument that media reports sufficed to put plaintiffs on notice because "there is no evidence that any of the plaintiffs read any of those articles or even received any of those newspapers.").

The Court further notes that even assuming the Bells saw these media articles, it is plausible that the articles would not have put the Bells on notice because the Bells allege they had no idea that Infuse was used in Scott Bell's surgery. This point distinguishes this case from *Soliman v. Philip Morris Inc.*, 311 F.3d 966 (9th Cir. 2002). There, a California plaintiff brought suit against a tobacco company claiming that smoking had injured him. *Id.* at 969. The company moved for dismissal on statute of limitations grounds because the plaintiff had smoked for thirty-some years before filing his claim and did not qualify for the delayed discovery rule because he should have been on notice of the health hazards of smoking long before filing his claim. *Id.* at 970. The district court granted the motion to dismiss, and the Ninth Circuit affirmed, holding that a "smoker who is injured by a product he believed to be safe has reason at least to suspect that its manufacturer or seller has done something wrong." *Id.* at 972. The court held the limitations period began when the

plaintiff should have known he was addicted. *Id.* at 973. Despite the fact that the plaintiff claimed he didn't realize he was addicted until the year 2000, "a reasonable person would have discovered it sooner" given that "the dangers of nicotine addiction have been in the public spotlight for many years." *Id.* at 973, 975. *Soliman* is inapposite here because Soliman obviously knew he was smoking. In contrast, Scott Bell had no idea that Infuse had been used in his surgery because his doctors never told him it was and actually indicated to him in 2007, before the media coverage of Infuse in 2008, that his injuries were caused by a biological phenomenon. Thus, it is plausible that Scott Bell would not have known that media reports on Infuse, to the extent he saw them, applied to him.

In sum, the Court cannot conclude that the only reasonable inference to be drawn from the Bells' allegations is that a reasonable person in Scott Bell's position would have been on inquiry notice at the latest by 2008. Thus, Defendants have not met their burden of showing that the Bells suspected or should have suspected the wrongful cause of Scott Bell's injuries by 2008.

Second, the Court explains why the Bells have pled sufficient facts showing (1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence. "Once the plaintiff has a suspicion of wrongdoing, and therefore an incentive to sue, she must decide whether to file suit or sit on her rights. So long as a suspicion exists, it is clear that the plaintiff must go find the facts; she cannot wait for the facts to find her." *Jolly*, 44 Cal.3d at 1111. Thus, in California, a "plaintiff whose complaint shows on its face that [her] claim would be barred without the benefit of the discovery rule must specifically plead facts to show (1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence." *Fox*, 35 Cal.4th at 808 (citation omitted). The burden is "on the plaintiff to show diligence; conclusory allegations will not withstand demurrer." *Id.* (internal quotations omitted).

The Bells have met their burden with respect to the first prong of the *Fox* test by alleging the time and manner of discovery, i.e., when they were on inquiry notice of Defendants' alleged wrongdoing. Their complaint makes clear how and when Scott Bell discovered facts sufficient to put the Bells on notice. The complaint alleges Scott Bell was alerted in April 2012 by his mother

based on a television commercial she saw, after which time Scott Bell contacted a lawyer to investigate. Bell Complaint ¶ 297. The Bells have also pled sufficient facts with respect to the second prong of the *Fox* test by alleging that they acted with reasonable diligence to discover the cause of his injuries and were unable to have made earlier discovery despite such diligence. Bell Complaint ¶ 298. Standing alone, such allegations would be deemed conclusory and would fail to withstand dismissal. However, the Bells allege additional facts that support their allegations, as elaborated above. For example, they allege that they made "numerous consultations with Mr. Bell's medical providers," *id.*, that his doctor never informed him Infuse was to be used in the surgery, that Scott Bell's consent form never mentioned Infuse but implied that the bone was to be taken from his iliac crest instead, that his doctor told him his pain was due to a "biological phenomenon" and did not mention it could be caused by any product used during his surgery. *Id.* at ¶¶ 290-296. These allegations could support the inference that a reasonably diligent person would not have made an earlier discovery by investigating further, given that Scott Bell may have reasonably relied on his doctor's statement that the cause of his injuries was just a "biological phenomenon." Accordingly, the Court finds that the Bells have pled sufficient facts showing their inability to have made earlier discovery despite reasonable diligence.

Finally, the Court notes that four of the cases cited by Defendants, namely *Jolly*, *Norgart*, *Fox*, and *Gutierrez*, are readily distinguishable from the instant case. "In both *Jolly* and *Norgart*, the court emphasized that the plaintiffs had ample reason to suspect the basis of their claims." *Fox*, 35 Cal.4th at 814. In fact, in those cases, as well as in *Gutierrez*, the plaintiffs actually admitted that they suspected the defendant's wrongful conduct at a time that rendered their claims time-barred. *See Jolly*, 44 Cal.3d at 1112; *Norgart*, 21 Cal.4th at 405–6; *Gutierrez*, 39 Cal.3d at 895-97 (noting that plaintiff conceded in her deposition that "she felt [as early as 1978] that the surgeons had 'done something wrong' to her."). In this case, on the other hand, Scott Bell's medical providers did not inform him that Infuse was used in his surgery and instead implied the bone was to be taken from his iliac crest, and also told him that his post-surgery pain was the result of a "biological phenomenon" and his unique reaction to the surgery. Additionally, *Jolly* and *Norgart*

were decided at the summary judgment stage, meaning the court was "presented with a more fully developed factual basis for determining when and how the plaintiff discovered an injury, whether the plaintiff conducted a reasonable investigation, when such an investigation would have brought to light the factual basis for the cause of action ... and whether the plaintiff could have discovered the factual basis for a cause of action earlier by exercising reasonable diligence." *Fox*, 35 Cal.4th at 810. On the other hand, this motion has been brought at the pleading stage, so the Court must take all of the Bells' factual allegations as true. Finally, unlike the plaintiff in *Fox*, the Bells did not fail to "allege facts explaining why [they] did not have reason to discover earlier the factual basis of" their claims. *Id.* at 806.

Because the Court finds that the Bell complaint alleges sufficient facts to satisfy the pleading requirements of the discovery rule, the Court rejects Defendants' argument that the Bell complaint must be dismissed as time-barred.

B. Analysis of both Richard Eidson and the Bells' Fraudulent Misrepresentation/Fraud in the Inducement Claims, Negligent Misrepresentation Claims, Strict Liability Failure to Warn Claims, and Negligent Failure to Warn Claims

Both Eidson and the Bells bring the same four causes of action: (1) fraudulent misrepresentation/fraud in the inducement; (2) negligent misrepresentation; (3) strict products liability failure to warn; and (4) negligent failure to warn. The Bells also bring a fifth cause of action: loss of consortium on behalf of April Bell. The Court addresses April Bell's consortium claim in Part IV.C below. In this section, the Court addresses both Eidson and the Bells' fraudulent misrepresentation/fraud in the inducement claims, negligent misrepresentation claims, strict liability failure to warn claims, and negligent failure to warn claims. Defendants raise the exact same arguments against each of these four claims in their motion to dismiss the Eidson complaint and their motion to dismiss the Bell complaint. Thus, the Court addresses Defendants' arguments together with respect to both Eidson and the Bells' claims below.[6] The Court refers collectively to Eidson and the Bells as "Plaintiffs" below.

[6] For purposes of citations, the Court refers only to the Eidson complaint and the Eidson MTD, Eidson Opp'n, and Eidson Reply throughout the rest of this section, although the reader should

Defendants argue that all of Plaintiffs' claims are expressly and impliedly preempted, Eidson MTD at 4-18, and that their fraud claims are not pled with the requisite particularity and fail to state a claim under California law. Eidson MTD at 19-21. Plaintiffs respond that their claims are not preempted, are pled with the requisite particularity, and state valid claims under state law. *See generally* Eidson Opp'n. The Court discusses each of Defendants' three arguments in turn below.

1. Preemption of Plaintiffs' Claims

The Court first addresses whether each of Plaintiffs' claims are expressly or impliedly preempted under federal law.[7]

a. Fraud-based claims: fraudulent misrepresentation/fraud in the inducement claim and negligent misrepresentation

The Court will consider Plaintiffs' two fraud-based claims together: Plaintiffs' fraudulent misrepresentation/fraud in the inducement claim and negligent misrepresentation claim. The Court concludes that neither claim is expressly or impliedly preempted.

In its October 3, 2013 Order, the Court noted that Eidson's original complaint was unclear as to precisely what conduct by Defendants formed the basis of Eidson's fraud-based claims. The two fraud-based claims evaluated in the October 3, 2013 Order were the fraudulent misrepresentation/fraud in the inducement claim and strict products liability misrepresentation claim. The Court held that to the extent Eidson's fraud-based claims alleged misrepresentations or

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bear in mind that the Court intends to refer as well to the identical sections in the Bell MTD, Bell Opp'n, Bell Reply, and Bell complaint. The briefing by both parties in both cases is substantively identical except with respect to the arguments concerning the statute of limitations issue and loss of consortium claim in the Bells' case, which do not appear in the parties' briefing for the Eidson case. The Bell complaint and Eidson complaint are also substantively identical except for the fact sections regarding Scott Bell and Eidson's surgeries and the additional allegations in the Bell complaint regarding the Bells' delayed discovery of Defendants' alleged wrongdoing and April Bell's loss of consortium claim.

[7] In its October 3, 2013 Order, the Court held that the first prong of the *Riegel* express preemption test was "clearly met" because the PMA process subjected Infuse to FDA "requirements" within the meaning of *Riegel*. *See Eidson*, 2013 WL 5533081 at *8 ("the Infuse Device was approved by the FDA, and such PMA imposes federal 'requirements' that are specific to the device"). Defendants do not challenge this holding. Thus, the Court adheres to its previous conclusion and considers *Riegel*'s threshold prong met. The second prong of *Riegel*'s express preemption test – whether Plaintiffs' claims are "different from, or in addition to" or "parallel to" federal requirements – will be addressed separately for each of Plaintiffs' claims.

omissions in the FDA-approved warning labels accompanying Infuse, such claims were expressly preempted because "requiring Defendants to alter the Infuse Device's warnings and label in order to provide extra warnings beyond those already approved during the PMA process would impose labeling and warning requirements 'different from, or in addition to' federal requirements." *Eidson*, 2013 WL 5533081 at *9. The Court held that if, on the other hand, Eidson's fraud-based claims alleged Defendants made misrepresentations or omissions in the course of promoting Infuse for off-label use, such claims were not expressly or impliedly preempted. *See id*. at *10-11. As a result, the Court denied Defendants' motion to dismiss Eidson's fraud-based claims.

After the October 3, 2013 Order, Eidson amended his complaint to allege two fraud-based claims: fraudulent misrepresentation/fraud in the inducement, and negligent misrepresentation. The first, his fraudulent misrepresentation/fraud in the inducement claim, is the same as in his original complaint because he left it unaltered. The second, negligent misrepresentation, is a new claim because Eidson changed his original strict products liability misrepresentation claim to a negligent misrepresentation claim. The Bells also have amended their complaint to allege two fraud-based claims: fraudulent misrepresentation/fraud in the inducement, and negligent misrepresentation. The Bells' fraudulent misrepresentation/fraud in the inducement claim is substantively identical to the fraudulent misrepresentation/fraud in the inducement claim in Eidson's amended complaint, and the Bells' negligent misrepresentation claim is substantively identical to the negligent misrepresentation claim in Eidson's amended complaint.

As to the Plaintiffs' first fraud claim, fraudulent misrepresentation/fraud in the inducement, Defendants urge dismissal on the grounds that this claim "still appears to challenge the sufficiency of the Infuse Device FDA-approved labeling." Eidson MTD at 7. Plaintiffs' oppositions suggest rather that this claim is based on fraudulent conduct in the course of off-label promotion. Eidson MTD at 4. As to the second fraud claim, negligent misrepresentation, that claim alleges that Defendants negligently made misrepresentations or omissions in the course of promoting Infuse for off-label use. Eidson Complaint ¶¶ 318-328. Defendants urge dismissal of this claim on the

grounds that *any* cause of action based on off-label promotion is expressly and impliedly preempted. Eidson MTD at 15, 17.

The Court analyzes Defendants' challenge to the Plaintiffs' two fraud-based claims together below and concludes that Defendants have not provided any persuasive reason for the Court to change its original conclusion in its October 3, 2013 Order that the fraud-based claims are not expressly or impliedly preempted to the extent they are based on fraudulent conduct in the course of off-label promotion.

i. Express preemption

Plaintiffs' fraudulent misrepresentation/fraudulent inducement and negligent misrepresentation claims are not expressly preempted because they impose state tort law duties that parallel federal requirements. Defendants argue that because off-label promotion is not necessarily a violation of federal law, state claims based on such promotion cannot be parallel to federal requirements. Eidson MTD at 13-14. However, as the Court noted in its October 3, 2013 Order, courts in the Ninth Circuit have generally held that device manufacturers are prohibited by federal law from promoting or advertising off-label use because such promotion is deemed to be false or misleading. *See Eidson*, 2013 WL 5533081 at *10; *Carson v. Depuy Spine, Inc.*, 365 Fed. Appx. 812, 815 (9th Cir. 2010) ("[W]hile doctors may use a drug or device off-label, the marketing and promotion of a Class III device for an unapproved use violates Section 331 of the FDCA."); *In re Epogen & Aranesp Off–Label Marketing & Sales Practices Litigation*, 590 F.Supp.2d 1282, 1287 (C.D. Cal. 2008) ("Under FDA regulations, drug manufacturers are prohibited from promoting off-label uses of prescription drugs."). Thus, as this Court previously explained, the duties underlying these two fraud claims are not "different from, or in addition to" the federal requirement banning off-label promotion because there is "no likelihood that Defendants could be held liable under [the] state law without having violated [] federal law." *Eidson*, 2013 WL 5533081 at *10 (citation omitted).

Even assuming off-label promotion per se does not constitute a violation of federal law as Defendants argue, *see* Eidson MTD at 13-14,[8] Defendants have advanced no authority suggesting that federal law permits false and misleading off-label marketing, and there is in fact law to the contrary. In holding that fraud claims based on Medtronic's promotion of Infuse escaped express preemption, the court in *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166 (C.D. Cal. 2013), held that federal law requires that advertising beyond the subject device's label not be false or misleading. *Id*. at 1179-80.[9] Thus, here, even assuming truthful off-label promotion does not violate federal law, Plaintiffs' claims still escape express preemption because they allege that specific aspects of Defendants' promotion activities were false or misleading. For example, Plaintiffs allege Defendants knowingly marketed Infuse in misleading ways, such as by paying kickbacks to "opinion leaders" to directly advocate off-label use of Infuse to other spine surgeons without disclosing their financial relationship with Defendants and bankrolling falsified medical studies and articles. Eidson Complaint ¶¶ 104, 119-122. Accordingly, the Court concludes that the state tort law duties underlying Plaintiffs' claims are not "different from, or in addition to" federal requirements, which unquestionably ban fraudulent marketing.

Other courts that have confronted these very same issues in cases involving these very same Defendants have similarly held that fraud-based claims alleging deceptive off-label promotion escape express preemption. *See, e.g.*, *Alton v. Medtronic, Inc.*, 3:13-CV-409-PK, 2013 WL 4786381 (D. Or. Sept. 6, 2013); *Kashani-Matts v. Medtronic, Inc.*, 2013 WL 6147032 (C.D. Cal. Nov. 22, 2013) ("To the extent that Plaintiff's fraud claims are based on alleged misrepresentations and omissions Medtronic made while promoting and marketing the Infuse Device, such claims

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[8] Courts have reached different conclusions as to whether *truthful* off-label marketing violates federal law. *Compare Dawson v. Medtronic, Inc.*, 3:13-CV-663-JFA, 2013 WL 4048850 (D.S.C. Aug. 9, 2013) ("This court is not convinced that off-label promotion violates the FDCA"), *with In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008) ("Differently put, (truthful) off-label promotion of a drug . . . violates the FDCA.").

[9] A device under the MDA is defined as "misbranded" if its advertising is false or misleading in any particular way. 21 U.S.C. § 352(q). The FDCA prohibits the introduction into interstate commerce of any misbranded device. 21 U.S.C. § 331(a). Accordingly, any false or misleading promotion of a device that is used in interstate commerce violates federal law.

could survive preemption"); *Scovil v. Medtronic, Inc.*, 2014 WL 502923 (D. Ariz. Feb. 7, 2014) (holding that claim based on false statements made to doctors in promoting Infuse for off-label use escapes express preemption); *Hawkins v. Medtronic, Inc.*, 2014 WL 346622 (E.D. Cal. Jan. 30, 2014) (same). Accordingly, the Court finds Plaintiffs' fraudulent misrepresentation/fraud in the inducement and negligent misrepresentation claims to be parallel to federal requirements, and thus not expressly preempted.

ii. Implied Preemption

The Court also finds that Plaintiffs' fraudulent misrepresentation/fraudulent inducement claim and negligent misrepresentation claims based on misleading off-label promotion are not impliedly preempted, because, as held in this Court's October 3, 2013 Order, such claims are "based on state common law tort duties that exist independently from the FDCA and not solely by virtue of the FDCA." *Eidson*, 2013 WL 5533081 at *11 (citing *Buckman*, 521 U.S. at 353, which holds that so long as a state law claim exists independently of federal requirements and does not exist "solely by virtue" of those federal requirements, there is no implied preemption).

Defendants ask the Court to reconsider this holding, arguing that *Perez v. Nidek Co., Ltd*, 711 F.3d 1109 (9th Cir. 2013), controls and suggests that Plaintiffs' "claims based on off-label promotion are impliedly preempted[.]" Eidson MTD at 18. The Court disagrees. In *Perez*, the Ninth Circuit held that a fraud claim against a medical device manufacturer was impliedly preempted pursuant to *Buckman*. The plaintiff alleged that the manufacturer of a laser approved by the FDA for use in nearsightedness surgery had modified the laser to allow it to be used in farsightedness surgery as well, despite the fact that the FDA had not yet approved it for that use. *Perez*, 711 F.3d at 1112. The plaintiff also alleged that the manufacturer knew doctors were using the laser off-label to treat farsightedness, *id.*, and that the manufacturer failed to disclose to patients that the device was not approved for such use despite knowing that patients would believe the device was FDA-approved for their surgeries. *Id* at 1117. The Ninth Circuit reasoned that the plaintiff's claims were not grounded in preexisting state law, and thus were impliedly preempted,

because "[l]ike the fraud-on-the-FDA claims in *Buckman*,[10] Perez's fraud by omission claim exist[s] solely by virtue of the FDCA." *Perez*, 711 F.3d at 1119. The court reasoned that because the plaintiff had challenged *only* the failure of the manufacturer to warn patients that a particular use was not FDA-approved, his claim did not implicate an independent state law duty. *Id.* The omission at issue – the "scope of PMA approval" as to off-label use – could only give rise to liability because of the existence of the FDCA approval process. *Id*. The court held that as in *Buckman*, the existence of the federal enactment was a critical element of plaintiff's case. *Id*.

Perez is easily distinguishable. Perez's claim was based solely on the device manufacturer's fraud by omission – failure to notify patients that the device was not approved by the FDA for certain off-label uses. *Id*. at 1112-13. Unlike Perez, Plaintiffs are not accusing Defendants simply of creating a product capable of off-label use and selling it to hospitals knowing it would be used unsafely without warning patients that off-label use was not FDA-approved. Rather, Plaintiffs allege that Defendants engaged in affirmatively fraudulent conduct when promoting Infuse for off-label use. Defendants are accused not of simply selling a device they know will be used off-label as in *Perez*, but of falsifying medical research and making statements via sales representatives and opinion leaders that knowingly understate the dangers of off-label use of Infuse. The omissions of which Plaintiffs complain are not simply the failure to warn patients of the fact of non-approval by the FDA, but failure to warn patients of known dangers associated with off-label Infuse usage. The main point here is that California common law unquestionably prohibits commercial

[10] In *Buckman*, plaintiffs who suffered injuries from the use of bone screws in spinal surgery brought state law fraud actions against a consultant who secured FDA approval for the screws. The plaintiffs claimed that the defendant secured FDA approval only by fraudulently misrepresenting the intended use of the screws during the application process, thereby causing the FDA to wrongly grant approval and leading to plaintiffs' injuries. *Buckman*, 531 U.S. at 347. The Supreme Court held such state law fraud claims were impliedly preempted under the MDA, as they amounted to nothing more than attempted private enforcement of the FDCA and thus "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id*. at 350. The Supreme Court suggested that the only types of state law claims that could survive implied preemption under the MDA were those that relied "on traditional state tort law which had predated the federal enactments in questions [sic]." *Id*. at 353. Claims based solely on an applicant's misstatements or omissions to the FDA during the approval process fail to meet that requirement, as they "exist solely by virtue of the FDCA disclosure requirements." *Id*.

misrepresentations and omissions such as those alleged here, *see Hauter v. Zogarts*, 14 Cal. 3d 104, 120 Cal. Rptr. 681, (1975) (affirming imposition of fraud liability on manufacturer who misrepresented safety of product), and thus Plaintiffs' state law claims predate and arise independently of the federal regulations and do not exist solely by virtue of the FDCA. In fact, *Perez* explicitly noted that the plaintiff was "not barred from bringing *any* fraud claim related to the surgeries, [although] he cannot bring a claim that rests solely on the non-disclosure to patients of facts tied to the scope of PMA approval." *Id*. at 1119-20 (emphasis in original).

Indeed, courts in the Ninth Circuit have distinguished the claim at issue in *Perez* from fraud claims based on off-label promotion of Infuse, holding that the latter claims are not impliedly preempted. *See, e.g.*, *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013) ("As an initial matter, Plaintiff's fraudulent advertising claims are not impliedly preempted under *Buckman* because they are moored in traditional state common law that exists independently from the FDCA."); *Scovil*, 2014 WL 502923 (finding fraud claims based on false statements in off-label promotion not preempted because they are "rooted in traditional state common law claims"); *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 994-95 (D. Ariz. 2013) (holding fraud claims not impliedly preempted because plaintiff could bring a claim against Medtronic "for knowingly concealing information in off-label promotion even if off-label promotion was legal under federal law."). Accordingly, the Court finds that Plaintiffs' fraudulent misrepresentation/fraudulent inducement claim and negligent misrepresentation claims are not impliedly preempted.

b. Failure to Warn Claims: Strict Liability Failure to Warn and Negligent Failure to Warn

Plaintiffs bring state law causes of action for strict liability failure to warn and negligent failure to warn. Eidson Complaint ¶¶ 303-17, 329-42. In its October 3, 2013 Order, the Court was uncertain as to what precise theory formed the basis of Eidson's strict liability failure to warn claim, but surmised two possible theories. To the extent the claim was based on Defendants' failure to include warnings beyond those in the FDA–approved label or failure to issue appropriate warnings regarding the dangers of off-label use, the claim was expressly preempted. *Eidson*, 2013

WL 5533081 at *12. To the extent it was instead based on Defendants' failure to report to the FDA adverse events regarding the dangers of off-label use, the Court found it was not expressly or impliedly preempted but nonetheless dismissed the claim for failure to establish a causal nexus between Eidson's injury and Defendants' conduct. *Id*. Subsequent to the Court's October 3, 2013 Order, both Eidson and the Bells amended their complaints to make clear that both their strict liability *and* negligent failure to warn claims are now each based on the same "three theories." Eidson Complaint ¶¶ 309, 336. In its analysis below, the Court concludes that Plaintiffs' failure to warn claims based on their first two theories – "overpromotion" and deceptive off-label promotion – are expressly preempted. The Court concludes that Plaintiffs' third theory premised on Defendants' failure to report adverse events to the FDA, however, escapes preemption.

i. "Overpromotion"

Plaintiffs' first theory underlying their failure to warn claims alleges that "MEDTRONIC breached its duty by overpromoting INFUSE® to Plaintiff and Plaintiff's physicians for use in off-label procedures." Eidson Complaint ¶¶ 309(a), 336(a). The Court concludes that because these claims challenge the sufficiency of the FDA-mandated warnings issued by Defendants, Plaintiffs' failure to warn claims based on an overpromotion theory are expressly preempted.[11]

Plaintiffs allege that "[a]ny warnings MEDTRONIC may have issued concerning the dangers of off-label use […] were insufficient *in light of* MEDTRONIC'S contradictory prior, contemporaneous, and continuing illegal promotional efforts and overpromotion." Eidson Complaint ¶ 309a (emphasis added). The California Supreme Court has interpreted state law failure to warn claims sounding in "overpromotion" as one way to attack a warning that is facially sufficient to satisfy a manufacturer's duty to warn, but the efficacy of which is undermined by aggressive promotion by the manufacturer. *See Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65, 507 P.2d 653, 661 (1973) ("Although the manufacturer or supplier of a prescription drug has a duty to adequately warn the medical profession of its dangerous properties or of facts which make it likely to be dangerous, an adequate warning to the profession may be eroded or even nullified by

[11] The Court does not reach the question whether Plaintiffs' failure to warn claims based on overpromotion are also impliedly preempted.

overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given."). Here, Plaintiffs' claims embrace such a theory by arguing that the FDA-mandated warnings were rendered insufficient by Defendants' excessive promotional activities. The Court concludes this renders these claims expressly preempted because they impose greater warning requirements on Defendants than the FDA requires. To state it differently, if Plaintiffs' state law claims were allowed to proceed to trial, a jury could hold Defendants liable for warnings they issue regarding Infuse that fully comply with FDA requirements simply because they are rendered "insufficient" as a result of Defendants' excessive promotion activities. Imposing such a state law duty, then, would establish requirements "different from, or in addition to" the federal law governing medical devices, and the state law duty is preempted.[12]

ii. Deceptive Off-label Promotion

Plaintiffs' second theory alleges that "MEDTRONIC breached its duty in that, in the course of promoting INFUSE® for off-label use (a use which the FDA had not reviewed or approved and for which the FDA had not reviewed or approved any written warnings), MEDTRONIC both affirmatively misrepresented and omitted information regarding the risks of the very off-label use MEDTRONIC was promoting." Eidson Complaint ¶¶ 309(b), 336(b). This Court held in its October 3, 2013 Order that a failure to warn claim based on Defendants' failure to issue appropriate warnings regarding the dangers of off-label use beyond those required by the FDA is expressly preempted because a "failure to warn claim that imposes obligations on Defendants beyond those imposed during the PMA process … imposes warning requirements 'in addition to' federal requirements." *Eidson*, 2013 WL 5533081 at *12 (citation omitted). Plaintiffs have

[12] Plaintiffs' oppositions do not provide any argument with respect to Plaintiffs' overpromotion theory. Defendants argue that Plaintiffs' failure to warn claims premised on an overpromotion theory must be dismissed because overpromotion "is not a cause of action in California." Eidson MTD at 10 n.4. Defendants are incorrect. California courts have approved jury verdicts on failure to warn claims based on an overpromotion theory such as the one Plaintiffs raise here. *See, e.g.*, *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 507 P.2d 653 (1973) (manufacturer of prescription drug could be held liable where excessive promotion undermined the efficacy of its otherwise adequate warning labels).

presented no persuasive reason for the Court to revisit that holding. Plaintiffs' argument is essentially that this Court's prior Order held that the "strict liability – misrepresentation" claim escaped preemption to the extent it was based on misrepresentations made during Defendants' off-label promotion activities. Eidson Opp'n at 7-9. Plaintiffs insist that they have merely "reorganized" the "strict liability – misrepresentation" cause of action as "failure to warn" claims, and that these "failure to warn" claims should thus benefit from the Court's prior holding that misrepresentation claims can escape preemption. *Id* at 8. Plaintiffs' argument fails, as explained below.[13]

Preemption analysis hinges on the extent to which state law liability can be imposed on a Defendant who has complied fully with the FDA requirements. *See Riegel*, 552 U.S. at 322. In other words, the MDA's preemption provision invalidates only state law duties that would impose requirements "different from, or in addition to" the requirements imposed on a medical device by the FDA. 21 U.S.C. § 360(c). Only if violation of a state law duty necessarily violates the federal requirements as well can the state law claim escape express preemption, because such a state law would not impose any requirements different from or in addition to what federal law already mandates. *See Riegel*, 552 U.S. at 321-22. Accordingly, this Court's prior reasoning in holding that the "strict liability – misrepresentation" claim was not preempted hinged on the fact that because FDA requirements prohibit false or misleading promotion of medical devices, any conduct giving rise to state law liability for fraud would by necessity constitute a violation of federal law. *See Eidson*, 2013 WL 5533081 at *10-11. California's cause of action for failure to warn, in contrast, requires *no showing* that a defendant engaged in any misleading or deceptive misrepresentation or omission. *See* California Civil Jury Instructions 1205 & 1222 (setting out elements of strict liability and negligent failure to warn, none of which include fraudulent conduct). As such, Plaintiffs' "reorganizing" does not save their failure to warn claims from express preemption because Defendants could be held liable under California law for conduct – i.e. for failure to warn – that does not violate the FDCA. In other words, if Plaintiffs' claims were to survive preemption, a jury

[13] The Court does not reach the question whether Plaintiffs' failure to warn claims based on deceptive off-label promotion are also impliedly preempted.

could find that Defendants' promotional activities did not contain material misrepresentations or omissions, yet still impose liability for failure to warn about the dangers of Infuse.

Moreover, every district court to apply California law to analogous facts has held that California's failure to warn cause of action is preempted. *See Houston*, 957 F. Supp. 2d at 1177 ("For Plaintiff to prevail, a jury would have to find either that Defendants were required to include warnings beyond those in the FDA-approved label for the Infuse Device, or that Defendants were obligated to issue post-sale warnings … In either case, Plaintiff aims to foist upon Defendants labeling or warning requirements 'in addition to' what federal law requires"); *Hawkins*, 2014 WL 346622, at *14-15 (holding California state law failure to warn claims for off-label promotion of Infuse expressly preempted); *Kashani-Matts*, 2013 WL 6147032, at *4 (same). California state courts have followed suit. In *Coleman v. Medtronic*, for example, the California court of appeal affirmed a lower court's dismissal of failure to warn claims based on precisely the same off-label promotion of Infuse at issue in this case. 223 Cal. App. 4th 413, 430-31 (Cal. App. 2d. Dist. 2014), *cert. granted,* 2014 WL 1714946 (Apr. 30, 2014). Accordingly, the Court concludes that Plaintiffs' failure to warn claims based on off-label promotion of Infuse are expressly preempted.

iii. Failure to Report Adverse Events to FDA

a. Express and Implied Preemption

Plaintiffs' third theory underlying their failure to warn claims is that "MEDTRONIC breached its duty in that it failed to warn Physicians by failing to communicate the growing number of adverse events [regarding off-label use] to the FDA from 2002 to 2011, as it was required to do by federal law." Eidson Complaint ¶¶ 309(c); 336(c). The Court's October 3, 2013 Order held that Eidson's strict liability failure to warn claim based on failure to report adverse events to the FDA escaped both express and implied preemption. *Eidson*, 2013 WL 5533081 at *12-13. As the Court observed, federal law – 21 C.F.R. § 803.50(a) – requires that manufacturers report any information "reasonably suggest[ing]" that one of their devices "[m]ay have caused or contributed to a death or serious injury." As such, this Court reasoned that a state law duty requiring that Defendants warn the FDA of adverse events was "parallel to" the existing federal requirements. *Eidson*, 2013 WL

5533081 at *12. The Court also found no implied preemption, based on Ninth Circuit precedent, *see Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc). *Eidson*, 2013 WL 5533081 at *12-13. Defendants argue that Plaintiffs' failure to warn claims based on this third theory are expressly and impliedly preempted. Eidson MTD at 15, 18. The Court disagrees because Defendants present no compelling reason for the Court to reconsider its holdings in the October 3, 2013 Order.

As this Court previously held, *Stengel* is apposite and controlling as to both express and implied preemption because it involved highly analogous claims to those at issue here. In *Stengel*, the Ninth Circuit held that an Arizona state law negligence claim based on failure to report adverse events to the FDA regarding Defendants' device was not expressly preempted because the "state-law duty parallel[ed][the] federal-law duty" to report events to the FDA. *See Stengel*, 704 F.3d at 1223. Under Arizona law, a manufacturer's duty to warn consumers about known product dangers may be satisfied by a warning to third parties, if the nature of the warning and of the relationship between the third party and consumer means that a warning given to the third party could be expected to reach the ultimate user of the product. *Id.* ("Arizona law contemplates a warning to a third party such as the FDA."). Therefore, the court reasoned that Arizona state law paralleled federal requirements because it demanded the same conduct of manufacturers that federal law did – notifying the FDA of adverse events, where such notification could be expected to put doctors and patients on notice of the product's dangers.

Stengel also held that the state law claim escaped implied preemption, as the "state-law claim [was] independent of the FDA's pre-market approval process that was at issue in *Buckman*." *Id*. at 1233. Unlike the claim at issue in *Buckman*, the plaintiffs in *Stengel* were not suing simply to enforce FDA requirements; they were suing under the theory that the defendants' failure to report to the FDA directly violated their duty to warn consumers. The state law cause of action could thus exist independently of any federal requirement to report adverse events to the FDA. *See Stengel*, 704 F.3d at 1235 (Watford, J., concurring) ("[I]n contrast to *Buckman*, the Stengels' claim is grounded in a traditional category of state law failure-to-warn claims that predated the federal

enactments in question" and therefore their claim "does not exist solely by virtue of those enactments") (citing *Buckman*, 531 U.S. at 353).

Defendants ask the Court to reconsider its previous finding that Plaintiffs' claims are not expressly preempted, claiming *Stengel* is distinguishable because its reasoning was based on Arizona's state law duty to warn third parties while California state law does not require a similar duty to warn third parties rather than direct consumers. Eidson MTD at 15, 17. However, Defendants are wrong to make this distinction because California law – like the Arizona law at issue in *Stengel* – requires a manufacturer to discharge its duty to warn consumers by communicating warnings to a third party in circumstances where such a warning is necessary to put consumers on notice of the danger. *See Persons v. Salomon N. Am., Inc.*, 217 Cal.App.3d 168, 178 (1990) (duty to warn can be satisfied by warning a third party "[w]hen a manufacturer or distributor has no effective way to convey a product warning to the ultimate consumer."). Therefore, like the claims in *Stengel*, Plaintiffs' failure to warn claims parallel federal requirements because they demand the same conduct of manufacturers that federal law does – notifying the third party FDA of adverse events, where such notification could suffice to put doctors and patients on notice of the product's dangers. Thus, Plaintiffs' claims are not expressly preempted.

Defendants also argue that Plaintiffs' claims based on a failure to report adverse events to the FDA are impliedly preempted because the duty to report such events exists solely by virtue of the FDCA. Eidson MTD, at 18-19. The Court rejects this argument, as the Ninth Circuit confronted and rejected this argument in *Stengel*. California's duty to warn of product dangers – including its duty to warn third parties, if appropriate and necessary – exists independently of any federal law. Just as in *Stengel*, Plaintiffs are not attempting to act as a private enforcer of the FDCA. Rather, they are seeking to hold Defendants liable for violating their state law duty to warn them of known dangers, on the theory that reporting to the FDA would ultimately have put them on notice of the danger because adverse events are published in the MAUDE database.

Most lower courts – both federal and state – that have analyzed and applied *Stengel* to California state law failure to warn claims premised on a failure to report to the FDA have held that

the claims escape both express and implied preemption. *See, e.g.*, *Ramirez,* 961 F. Supp. 2d at 1002 (following *Stengel* and declining to dismiss a "failure to warn" claim premised on defendants' failure to report adverse events involving Infuse to the FDA); *Houston*, 2014 WL 1364455 (same); *Coleman*, 223 Cal. App. 4th at 429-30. In sum, the Court continues to follow *Stengel* and thus holds Plaintiffs' failure to warn claims premised on Defendants' failure to report adverse events to the FDA are not expressly or impliedly preempted.

b. Causal Nexus

While the Court's October 3, 2013 Order held that Eidson's failure to warn claims escaped preemption to the extent they were based on a failure to report adverse events to the FDA, the Court nonetheless dismissed those claims because Eidson had failed to show how the failure to report caused his injuries. *Eidson*, 2013 WL 5533081 at *13. To properly plead claims that escape preemption, "a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation." *Erickson v. Boston Scientific Corp*., 846 F.Supp.2d 1085, 1092 (C.D. Cal. 2011). This Court noted that Eidson had only alleged a single adverse incident that Defendants had failed to report, and that Eidson's failure to specify the date of this event left the Court with "no basis to evaluate whether the failure to report may have had a causal effect on Eidson's injuries." *Id*. Subsequent to that Order, the Bells and Eidson both changed their complaints to address this deficiency. Defendants now argue Plaintiffs have failed to cure this deficiency regarding causation. Eidson MTD at 2. The Court disagrees.

Plaintiffs have sought to cure this defect by referencing a study by a Dr. Carragee which finds that by April 2008, Defendants had reported only 262 of an estimated 50,000-250,000 adverse events involving the off-label use of Infuse. Eidson Complaint at ¶¶ 255, 309 (c)(iii)-(v). Plaintiffs also claim that "[t]he FDA maintains a MAUDE database on reported adverse events, which is a public database known to, and discussed in, the medical community, including Plaintiff's physicians" and that "[i]f MEDTRONIC had communicated adverse events to the FDA as required by law, this would have effectively warned plaintiff's surgeon of those adverse events –

both directly and through the discussion of those adverse events that would have followed in the literature and at meetings plaintiff's surgeon attended." *Id*. at ¶¶ 309(c)(iii)-(x), ¶¶ 336(c)(viii)-(x). Defendants cite to *Hawkins*, 2014 WL 346622, for the proposition that general allegations that a device manufacturer failed to report to the FDA are not sufficient to establish a causal nexus to a plaintiff's injuries stemming from off-label use. Eidson Reply at 4-5. In *Hawkins*, much like in Plaintiffs' original complaints, the court dismissed the plaintiff's claims because he had failed to provide specific dates of adverse events or show how the failure to report them caused his injuries. *See Hawkins*, 2014 WL 346622 at *8 ("Plaintiff generally alleges that Defendants failed to report adverse events to the FDA. He also generally alleges that these failures caused or contributed to his injuries. What is not alleged is any factual content that would support the causal nexus.").

In the instant case, Plaintiffs have amended their claims to include additional facts about the specific nature of Defendants' failure to report. As such, the reasoning in *Hawkins* no longer applies. By including facts relating to Dr. Carragee's study, Plaintiffs have shown that (1) Defendants underreported adverse events on a large scale, and (2) plaintiffs' surgeons would have had access to adverse reports if they were properly submitted. Eidson Complaint ¶¶ 249-254, 309(c)(iii)-(x), 336(c)(viii)-(x). At the pleading stage, these allegations are sufficient to support a reasonable inference that had Defendants made the required reports, Plaintiffs' physicians would have been put on notice of the danger of off-label use of Infuse and may have elected to conduct the surgeries differently. *Id*. at ¶ 314 ("Plaintiff's physician would not have [] used INFUSE® off-label by utilizing a posterior approach, using INFUSE for an off-label indication, and by using INFUSE® without an LT Cage and in a manner otherwise not approved by the FDA had they known of the true safety risks"). Other courts have allowed claims against these same Defendants to proceed based on Dr. Carragee's study. *See Houston*, 2014 WL 1364455 at *7-8 (finding that Dr. Carragee's study supported an inference of causation sufficient to survive a motion to dismiss).[14] In sum, the Court declines to dismiss Plaintiffs' failure to warn claims for failure to allege causation.[15]

[14] Defendants also question the validity of Dr. Carragee's study by claiming that Dr. Carragee is not impartial, Eidson Reply at 4 n.1, and attack the plausibility of Plaintiffs' assertion that accurate

2. Rule 9(b)

The Court now addresses Defendants' argument that Plaintiffs' fraud-based claims – fraudulent misrepresentation/fraud in the inducement and negligent misrepresentation – should be

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reporting would have convinced their surgeons to act differently because the Infuse label itself already warned of the dangers of off-label use and because Plaintiffs' complaints allege that the FDA issued a "Public Health Notification" warning about the dangers of off-label use before their surgeries. Eidson Reply at 5; Eidson MTD at 9-10. The Court does not find Plaintiffs' causation argument so implausible as to fail scrutiny under *Twombly*. Defendants' arguments are best resolved by a jury. *See Coleman*, 223 Cal. App. 4th at 420, 428–29 (holding in a similar case that the plaintiff's claim survived beyond the pleading stage in terms of alleging causation, though warning that the plaintiff would ultimately have to overcome the "causation hurdle" with proof at trial).

[15] Defendants also claim Plaintiffs have failed to allege causation with respect to all of Plaintiffs' claims based on "off-label" promotion. Eidson MTD at 8-10. Specifically, Defendants claim Plaintiffs make "no attempt to tie any statements or other activities allegedly constituting off-label promotion to [their] surgeon[s]," *id.*at 8, and that Plaintiffs "do[] not identify one event before [their] surger[ies] involving any so-called key opinion leaders in which off-label promotion allegedly took place." *Id*. at 9. The Court is not convinced. Plaintiffs' complaints allege several actions by Defendants that took place *prior* to plaintiffs' surgeries and which could have influenced the likelihood that his physician would use Infuse off-label. These include (1) kickbacks to physicians and opinion leaders between 1998 and 2003, Eidson Complaint ¶ 141; (2) improper activities by Defendants' sales force at unspecified times, but prior to August 2009 and therefore plausibly prior to Eidson's 2008 surgery and Bell's 2005 surgery, *id*. at ¶¶ 155-159; (3) misleading statements made by paid "opinion leaders" Timothy Kuklo and Rick Sasso in a 2006 conference call regarding the dangers of Infuse off-lable use, *id*. at ¶ 185; and (4) five allegedly falsified scientific journal articles paid for by Medtronic and published between 2003 and 2008, *id*. at ¶¶ 86, 186, 205, 212, 217. Defendants argue that none of the pre-surgery articles involved precisely the same off-label procedure that was used in the surgeries. Eidson MTD at 9. While this is true, it is implausible to assume that a doctor considering the risk of using Infuse in a lumbar fusion would totally discount any lessons to be learned from scientific articles discussing the risk of bony overgrowth in cervical fusions. Moreover, while Defendants are correct that Plaintiffs have failed to allege which of these specific misrepresentations their surgeons received and relied upon when deciding to use Infuse in an off-label way, Plaintiffs have alleged that their physicians attended meetings at which off-label use of Infuse was discussed, *id*. at ¶ 309(x), received unspecified advertisements by Defendants regarding the safety of Infuse for off-label use, *id*. at ¶ 336(ix), were trained and encouraged by Defendants to use Infuse off-label, *id*. at ¶ 286, and that they "did rely" upon Defendants' representations regarding the safety risks of Infuse when deciding to use Infuse in an off-label way, *id.* at ¶ 300. Plaintiffs have thus alleged wrongful conduct by Defendants that predated Plaintiffs' surgeries, upon any or all of which their physicians could plausibly have relied. The Court finds it inappropriate to dismiss this action at this stage for lack of causation before Plaintiffs have had had the benefit of discovery and have not yet had an opportunity to depose their physicians to determine which precise meetings they attended, articles they read, and promotions they received. Plaintiffs' voluminous complaints adequately suffice to put Defendants on notice of the activities Plaintiffs intend to prove caused their injuries.

dismissed because they are not pled with the necessary particularity under Federal Rule of Civil Procedure 9(b). Eidson MTD at 3, 19-20. Federal Rule of Civil Procedure 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The Court already held in its October 3, 2013 Order that Eidson's fraud-based claims – fraudulent misrepresentation/fraud in the inducement and strict products liability misrepresentation – satisfied Rule 9(b). *Eidson*, 2013 WL 5533081, at *11. Defendants ask the Court to reconsider this holding based on *Houston v. Medtronic*, 957 F. Supp. 2d at 1180. Eidson MTD at 20. That case similarly involved Medtronic defending against claims based on off-label marketing of the Infuse product, and was dismissed for insufficient particularity because the court found that the complaint failed to "allege the specific contents of those representations, when and where Defendants allegedly made them, and to whom they were made. Nor has Plaintiff alleged which parts of the misrepresentations were misleading, and *why* they are false." *Houston*, 957 F. Supp. 2d at 1180. The Court declines to change its conclusion because Defendants have advanced no persuasive reason to reconsider its prior conclusion that Eidson's fraud claims were pled with "voluminous particularity." *Eidson*, 2013 WL 5533081, at *11. The same goes for Defendants' challenge to the Bells' fraud claims because the Bells' allegations are identical to Eidson's allegations. Plaintiffs have not simply made general allegations of malfeasance; they have alleged facts relating to: (1) specific scientific articles funded by Medtronic, including their authors, dates of publication, and what information was misstated or omitted in them; (2) misleading statements and omissions made by named "opinion leaders" in the course of promotional activities," and (3) allegedly deceptive activities undertaken by Defendants' sales representatives. *See, e.g.*, Eidson Complaint ¶ 86 (noting 2004 study which falsely claimed that patients suffered no ill effects from bony overgrowth complications); *id*. at ¶ 185 (noting 2006 conference call in which "opinion leader" Rick Sasso understated esophageal complications from the use of Infuse in off-label procedures); *id*. at ¶ 167 (noting that Defendants instructed their sales representatives in how to "get around" restrictions in off-label promotion). The Court continues to

find that these allegations put Defendants on sufficient notice of the particular misconduct alleged to permit Medtronic to prepare a defense to Plaintiffs' claims.

Similar claims have withstood Rule 9(b) challenges in this Circuit. *See Alton*, 2013 WL 4786381 (holding, in nearly identical case regarding state law fraud claims regarding off-label promotion of Infuse, that fraud claims satisfied Rule 9(b)). In fact, *Houston*, cited by Defendants, now supports a denial of Rule 9(b) dismissal because after the court's dismissal, the plaintiff in that case amended her complaint by adding additional facts. *See Houston v. Medtronic, Inc.*, 2014 WL 1364455, at *8 (C.D. Cal. Apr. 2, 2014). That court very recently rejected Medtronic's renewed motion to dismiss, holding that Houston's amended complaint now satisfies Rule 9(b) because the plaintiff had added facts about specific studies and presentations. *See id.* at *9.[16] In sum, the Court holds that Plaintiffs have pled their fraud-based claims with sufficient particularity to survive a motion to dismiss.

3. Failure to State a Claim under California Law

Finally, the Court addresses Defendants' argument that Plaintiffs' fraud-based causes of action fail to state a claim under California law. Eidson MTD at 8, 21. Defendants assert that Plaintiffs' fraud claims are tantamount to a general "fraud-on-the-market" complaint in which a plaintiff seeks to hold a defendant liable for misrepresentations that mislead consumers generally rather than the plaintiff or the plaintiff's agent specifically. *Id.* The California Supreme Court has held that such "fraud-on-the-market" claims are not cognizable under California law; plaintiffs

[16] Defendants also argue that fraud claims similar to those Plaintiffs make here were dismissed for failure to satisfy Rule 9(b) in *Hawkins v. Medtronic, Inc.*, 1:13-CV-00499 AWI SK, 2014 WL 346622 (E.D. Cal. Jan. 30, 2014). Eidson Reply at 10. *Hawkins*, however, is distinguishable. There, the court relied on the fact that the plaintiff had alleged defendants engaged in off-label promotion via opinion leaders and Medtronic-funded articles, but noted that "nothing in the complaint points to specific content in those articles or statements made by the named opinion leaders that were allegedly false, or why the representations were untrue." *Hawkins*, 2014 WL 346622 at *12. In the instant cases, by contrast, Plaintiffs have adequately alleged specifics regarding the way in which such journal articles and opinion leader statements were false or misleading. With regard to Dr. Kuklo's 2008 article in the Journal of Bone and Joint Surgery, for example, Plaintiffs allege that the article falsely identified uninvolved surgeons as co-authors, suggested an inflated efficacy rate for Infuse, and reported positive results for a "ghost population" of patients that never existed. Eidson Complaint ¶¶ 192, 196, 197.

must plead that they or their agent relied on the misrepresentations in order to maintain an action sounding in fraud. *See Mirkin v. Wasserman*, 5 Cal. 4th 1082, 1091-1096 (1993).[17] Defendants' argument fails because Plaintiffs' complaints do plead reliance by their agents – i.e., their surgeons. Although Plaintiffs acknowledge that they do not allege specifically upon which articles, presentations, and promotional activities their surgeons relied in deciding to use Infuse in an off-label manner, Eidson Opp'n at 5, they explicitly allege their doctors relied upon Defendants' representations regarding the safety risks of Infuse when deciding to use Infuse in an off-label way. Eidson Complaint at ¶ 300. Further, the Court has not found any case holding that in order to survive a challenge that a plaintiff's claim is simply a generalized fraud-on-the-market claim, a plaintiff must identify the *specific* statements upon which the plaintiff or his agent relied from among a large number of fraudulent statements alleged in the complaint. To the contrary, California courts have generally held that where a plaintiff's fraud claim is based on a long-term promotional campaign involving a large number of false statements, the plaintiff is *not* required to identify in the pleadings precisely when each false statement was made and on which the plaintiff or his agent relied. *See Comm. On Children's Television, Inc. v. Gen. Foods Corp.*, 35 Cal. 3d 197, 218-19, 673 P.2d 660, 674 (1983) (reasoning that a long-term promotional campaign may persuade by "cumulative impact" rather than specific discrete false statements, and therefore plaintiffs "should be able to base their cause of action upon an allegation that they acted in response to an advertising campaign even if they cannot recall the specific advertisements."); *Morgan v. AT & T Wireless Servs., Inc.*, 177 Cal. App. 4th 1235, 1262, 99 Cal. Rptr. 3d 768, 790-91 (2009) ("[W]here a fraud claim is based upon numerous misrepresentations, such as an advertising campaign that is alleged to be misleading, plaintiffs need not allege the specific advertisements the individual plaintiffs relied upon."); *Whiteley v. Philip Morris Inc.*, 117 Cal. App. 4th 635, 680-81, 11 Cal.

[17] *Mirkin* recognized that "misrepresentations to the plaintiff may be communicated indirectly through an agent or third party," but the plaintiff must show that the third party relied on the misrepresentations. *Id.* at 1096. *See, e.g., Grinnell v. Charles Pfizer & Co.*, 274 Cal.App.2d 424, 441 (1969) (plaintiffs, who had not heard or read misrepresentations of pharmaceutical manufacturer, were allowed to sue manufacturer for breach of express warranty because the doctors who administered the drugs had relied on the manufacturer's representation and acted as the plaintiffs' agent);

Rptr. 3d 807, 844-45 (2004) (affirming verdict for plaintiff who successfully sued tobacco company for misleading advertising campaign, on grounds that plaintiff "did not have to prove that she saw or heard any *specific* misrepresentations of fact or false promises that defendants made.") (emphasis added). Thus, the Court rejects Defendants' argument that Plaintiffs' claims are simply generalized fraud-on-the-market claims.[18]

C. Analysis of April Bells' Loss of Consortium Claim

April Bell's loss of consortium claim alleges that as a result of Defendants' actions, her marital relationship with her husband has suffered. Bell Complaint at ¶ 356. In California, the spouse of an individual injured by a third party has a cause of action for loss of consortium: the loss of conjugal fellowship and sexual relations. *Rodriguez v. Bethlehem Steel Corp.*, 525 P.2d 669, 670 (Cal. 1974). A loss of consortium claim is derivative of and dependent on the spouse's negligence action. *Calatayud v. State of* California, 18 Cal.4th 1057 n.4 (1998).

Defendants argue that April Bell's loss of consortium claim fails as a matter of law because it is a derivative claim and "all of the claims upon which April Bell brings her claim are preempted and/or otherwise barred under California law." Bell MTD at 25. Thus, Defendants argue her claim is preempted as well. *Id.* The Court grants in part and denies in part Defendants' motion to dismiss April Bell's claim. To the extent April Bell's claim derives from those of Scott Bell's claims which this Court has found preempted in this Order, April Bell's claim is also preempted, and the motion to dismiss is GRANTED. However, to the extent that April Bell's claim derives from those of Scott Bell's claims which this Court has found not preempted, April Bell's claim is not preempted, and the motion to dismiss is DENIED.

V. CONCLUSION

With respect to the Eidson complaint, the Court DENIES Defendants' motion to dismiss Eidson's fraudulent misrepresentation/fraud in the inducement and negligent misrepresentation

[18] The Court also notes that it declines to dismiss this action at this stage for failure to adequately plead reliance in light of how Plaintiffs have not yet had the benefit of discovery and the opportunity to depose their physicians to determine which precise meetings they attended, articles they read, and promotions they received and relied upon.

claims based on fraudulent conduct in the course of off-label promotion because such claims are not expressly or impliedly preempted. The Court DENIES Defendants' motion to dismiss Eidson's failure to warn claims based on Defendants' failure to report adverse events to the FDA because such claims are not expressly or impliedly preempted. The Court GRANTS with prejudice Defendants' motion to dismiss Eidson's failure to warn claims based on Defendants' overpromotion of off-label use of Infuse and based on Defendants' deceptive off-label promotion because those claims are expressly preempted.

With respect to the Bell complaint, the Court DENIES Defendants' motion to dismiss the Bells' fraudulent misrepresentation/fraud in the inducement and negligent misrepresentation claims based on fraudulent conduct in the course of off-label promotion because such claims are not expressly or impliedly preempted. The Court DENIES Defendants' motion to dismiss the Bells' failure to warn claims based on Defendants' failure to report adverse events to the FDA because such claims are not expressly or impliedly preempted. The Court GRANTS with prejudice Defendants' motion to dismiss the Bells' failure to warn claims based on Defendants' overpromotion of off-label use of Infuse and based on Defendants' deceptive off-label promotion because those claims are expressly preempted. The Court GRANTS IN PART AND DENIES IN PART Defendants' motion to dismiss April Bell's loss of consortium claim.

IT IS SO ORDERED.

Dated: May 13, 2014

Lucy H. Koh

LUCY H. KOH
United States District Judge